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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,231	12/29/2000	Richard N. Ellison	7610-0040	8767
23980	7590	04/21/2004		
REED & EBERLE LLP 800 MENLO AVENUE, SUITE 210 MENLO PARK, CA 94025			EXAMINER TRAN, MY CHAU T	
			ART UNIT 1639	PAPER NUMBER

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,231

Applicant(s)

ELLSON ET AL.

Examiner

MY-CHAU T TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-58 and 81-84 is/are pending in the application.
- 4a) Of the above claim(s) 11-18,50-53,55,57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,19-49,54,56 and 81-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/29/00 & 7/31/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 1/29/04 is acknowledged and entered. Claims 1, 6-7, 9, 24, 54, 56 have been amended. It is noted that the status of claims 55, and 57-58 are incorrectly denoted in the claim listing because these claims are withdrawn from further consideration as being drawn to *nonelected species*.
2. Claims 2, and 59-80 are canceled by the amendment filed on 3/3/03.
3. Claims 1, 3-58, and 81-84 are pending.
4. Applicant has elected the following species for the elected invention (Claims 1-49, and 54-58):
 - a. A species of condition is temperature.

Election/Restrictions

5. Claims 11-18, 55, 57, and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected species*, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7, filed 9/18/02.

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6. Claims 50-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a *nonelected invention*, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 7, filed 9/18/02.

7. This application contains claims 50-53 are drawn to an invention nonelected with traverse in Paper No. 7, filed 9/18/02. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

8. The substituted formal drawings received on 7/31/03 that replaces figures 2A and 2B of the original drawings filed 12/29/00 are acceptable.

9. Claims 1, 3-10, 19-49, 54, 56, and 81-84 are treated on the merit in this Office Action.

Withdrawn Objections and /or Rejections

10. In view of applicant's amendments of claims 1 and 56, the previous rejection under 35 USC 112, first paragraph (written description) has been withdrawn.

11. In view of applicant's amendments of claims 1, 6-7, 9, 24, 54, 56, the previous rejections under 35 USC 112, second paragraph, have been withdrawn.

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12. In view of applicant's amendments of claims 1 and 56, the rejection of claims 1, 3-10, 19-33, 38-49, 54, 56, and 81-84 under 35 USC 102(b) as being anticipated by Nova et al. (US Patent 5,874,214) has been withdrawn.

13. In view of applicant's amendments of claims 1 and 56, the rejection of claims 1, 3-10, 19-49, 54, 56 and 81-84 under 35 USC 103(a) as being unpatentable over Nova et al. (US Patent 5,874,214) and of Wang et al. (US Patent 5,922,617) has been withdrawn.

Maintained Rejections

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

15. Claims 1, 3-10, 19-49, 54, 56 and 81-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The presently claimed device briefly recites a device comprising a plurality of different molecular probes attached to a surface and an integrated indicator, wherein the integrated indicator exhibits a detectable response when the device is exposed to a condition and removed from the condition.

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The recitation of 'the device is exposed to a condition and removed from the condition.' claimed in claims 1, 3, 54, and 56, have no clear support in the specification and the claims as originally filed. The specification in page 13 disclosed *'the indicator response to the condition is detectable for at least 1 minute after removing the indicator from the condition'* (line 6) is not support for *'the device is exposed to a condition and removed from the condition'*. Because the narrow limitation of the specification recites that the indicator is exposed to and removed from the condition, it does not support the broad limitation of the claim, which recites the device is exposed to a condition and removed from the condition. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of device is exposed to a condition and removed from the condition.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Response to Arguments

16. Applicant's argument directed to the above rejection under 35 U.S.C. 112, first paragraph (new matter), for claims 1, 3-10, 19-49, 54, 56 and 81-84 have been fully considered but they are not persuasive for the following reasons.

Applicant contends that "[W]ith the above amendments, all formality-based objections and rejections have been addressed" (i.e. applicant's amendments of claims 1, 6-7, 9, 24, 54, 56).

Applicant's arguments are not convincing since the amendments of claims 1, 54, and 56 does not address the issue of support for the recitation of 'the device is exposed to a condition and removed from the condition.' claimed in claims 1, 3, 54, and 56. Applicant did not provide

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where the limitation of 'the device is exposed to a condition and removed from the condition.' has clear support in the specification. Therefore, the rejection under 35 U.S.C. 112, first paragraph (new matter) is maintained.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 1, 3-10, 19-49, 54, 56, and 81-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The presently claimed device recites a substrate, a plurality of different molecular probes, and an integrated indicator. The substrate has a surface comprising a probe region and an indicator region.

The recitation of 'a surface comprises a probe region and an indicator region' claimed in claims 1, 54, and 56 has no clear support in the specification and the claims as originally filed. The specification in page 10 disclosed *'The term "discrete" is typically used herein in its ordinary sense and refers to a region of a substrate that constitutes a separate or distinct part with respect to another region of the substrate. Thus, one discrete region of a substrate such as the interior region is readily distinguishable from another region such as the surface.'* (lines 12-

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15) is not support for '*a surface comprising a probe region and an indicator region*'. Because the specification recites the definition of the term 'discrete', it does not support the structural limitation of the claim, which recites the surface of the substrate comprises a probe region and an indicator region. Therefore, the recitation of 'a surface comprises a probe region and an indicator region' lacks specification support.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 54, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Cargill et al. (US Patent 5,770,455).

The instant claim recites a device that comprises a substrate, molecular moieties, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region and the molecular moieties are attached to the probe region. The indicator exhibits the detectable response for at least one minute after removing the device from the condition and is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides. With regard to claim 54 the molecular moieties are nucleotidic molecular probes.

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Cargill et al. disclose labeled libraries of random oligomers (device) (col. 9, line 64 to col. 10, line 8). The labeled libraries of random oligomers comprise a synthesis support (substrate), an identifier tag (integrated indicator), and an oligomer library member (molecular moieties) (col. 11, lines 18-33; fig. 7). The synthesis support comprises different areas wherein the identifier tag and oligomer library member are attached (probe region and indicator region). The synthesis support has a plurality of oligomer library members attached (col. 11, lines 51-54). The oligomers include polynucleotides (col. 13, lines 27-48). The identifier tag would contain information of transformation events such as changes in temperature (col. 12, lines 14-45; col. 14, lines 37-52). Therefore, the device of Cargill et al. anticipates the presently claimed device.

21. Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Bioarray Solutions LLC ("Bioarray") (WO 98/53093).

The instant claim recites a device that comprises a substrate, molecular moieties, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region and the molecular moieties are attached to the probe region. The indicator exhibits the detectable response for at least one minute after removing the device from the condition and is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides.

Bioarray discloses labeled libraries of beads (device) (pg. 7, line 16-30). The libraries of beads comprise beads (substrate), color codes (integrated indicator), and compounds (molecular moieties) (pg. 17, lines 1-11; fig. 3). The bead comprises different areas wherein the color codes and compounds are attached (probe region and indicator region). The color codes would contain

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informations of events that occur with the compounds such as target binding and environmental monitoring (pg. 17, line 14-27; pg. 20, lines 7-27). Therefore, the device of Bioarray anticipates the presently claimed device.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 1, 3-10, 19-37, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cargill et al. (US Patent 5,770,455) and Wang et al. (US Patent 5,922,617).

The instant claim 1 recites a device that comprises a substrate, a plurality of different molecular probes, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region. The indicator

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exhibits the detectable response for at least one minute after removing the device from the condition and is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides. The different molecular probes are attached to the probe region and interact with a corresponding target.

Cargill et al. disclose labeled libraries of random oligomers (device) (col. 9, line 64 to col. 10, line 8). The labeled libraries of random oligomers comprise a synthesis support (substrate), an identifier tag (integrated indicator), and an oligomer library member (molecular moieties) (col. 11, lines 18-33; fig. 7). The synthesis support comprises different areas wherein the identifier tag and oligomer library member are attached (probe region and indicator region). The synthesis support has a plurality of oligomer library members attached (col. 11, lines 51-54). The oligomers include polynucleotides (col. 13, lines 27-48). The identifier tag would contain information of transformation events such as changes in temperature (col. 12, lines 14-45; col. 14, lines 37-52).

The device of Cargill et al. does not expressly disclose a plurality of different molecular probes on the surface of the substrate.

Wang et al. disclosed a device in which the microarray would contain 10 or more different probes (col. 2, lines 60-65). Wang et al. suggest that the number of individually addressable sites (probes) on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a plurality of different molecular probes on the surface of the

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substrate as taught by Wang et al. for the device of Cargill et al. One of ordinary skill in the art would have been motivated to include an array of 10 or more probes on the surface of the substrate in the device of Cargill et al. for the advantage of detecting multiple analytes since both Bioarray and Wang et al. disclose beads that are encoded with a binary code (Cargill: col. 10, lines 17-26; Wang: col. 7, lines 10-20). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Bioarray and Wang et al. because Wang et al. suggest that the number of probes on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11). Therefore, the choice of the number of probe on the surface of the substrate would depend on the availability of bound component.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
April 17, 2004


PADMASHRI PONDALURI
PRIMARY EXAMINER